

California Code of Regulations
Title 17. Public Health
Division 1. State Department of Health Services
Chapter 5. Sanitation (Environmental)
Subchapter 1. Engineering (Sanitary)
Group 13. Eviscerated Crab

Justification

Detailed Discussion of Each Regulation

Adopt Section 8056 to explain that the eviscerated crab program regulations apply to a processor who receives, holds, or eviscerates Dungeness crab or rock crab caught in areas subject to a Department Evisceration Order for commercial purposes in California. Approved processors, as defined in proposed section 8058, play a critical role in controlling the hazards so that the crab can be made safe for human consumption.

Adopt Section 8057 to make clear the different types of registrations and fees that are required for the eviscerated crab program. This section adds clarity by functioning as a roadmap to succinctly put in one place the various requirements a proposed crab processor must meet.

Subsection (a) makes clear that registration requirements for processors include several actions, including obtaining, maintaining, and renewing a processed food registration and paying fees for the registration.

Subsection (b) clarifies the requirement for processors to possess a valid crab evisceration registration. Processors must provide the Department with the most current contact information as this person serves as the point of contact for the Department concerning matters such as certificates, compliance with regulations, operational questions, recall effectiveness checks, inspection scheduling, notifications related to the growing area, and annual renewal notifications.

Subsection (c) relates to enforcement and accountability of the processors approved by the Department regarding Hazard Analysis Critical Control Point plans. This enables the Department to contact all new applicants, ownership changes, and relocations to establish if the applicant meets Hazard Analysis Critical Control Point plan requirements.

Adopt Section 8058 to provide operational definitions of terms used in the body of sections 8056 through 8067, thereby providing uniform interpretation of the terms associated with crab evisceration. Some terms used by the California Department of Fish and Wildlife are being adopted by the Department to ensure understanding of common terminology shared across jurisdictional lines within this jointly administered program.

Adopt the term “action level” to clarify the maximum concentration of domoic acid that is allowed in crab viscera or crab meat. The whole crab is adulterated and cannot be consumed when the concentration of domoic acid exceeds the action levels in the viscera and the meat. If the concentration of domoic acid exceeds the action level for crab viscera, but is below the action level for crab meat, the Department will consult with the Office of Environmental Health Hazard Assessment about issuing an Evisceration Order. The action levels for crab viscera and crab meat are expressed in parts per million (ppm) units according to Appendix 5 of Fish and Fishery Products Hazards and Controls Guidance.

Adopt the term “approved processor” to clarify that the processor met the minimum requirements set by the Department and received a registration from the Department to process crab subject to an Evisceration Order. It is also necessary to clarify that the registration pertains only to Dungeness crab or rock crab because the statutory definition of “processor” broadly applies to fish and fishery products.

Adopt the term “biotoxin management areas” as locations identified by the California Department of Fish and Wildlife, the California Environmental Protection Agency's Office of Environmental Health Hazard Assessment, and the Department. Information provided from the monitoring of these geographic areas ensures that regulatory efforts are targeted to areas most susceptible to biotoxin outbreaks, optimizing resource allocation and management strategies.

Adopt the term “commercial fisher” to clarify that the term has the same meaning as “commercial fisherman” in section 8040 of the California Fish and Game Code where “commercial fisherman” means a person who has a valid, unrevoked commercial fishing license issued pursuant to section 7850 of the California Fish and Game Code. This ensures uniform understanding of terms.

Adopt the term “crab” to clarify that only Dungeness crab and rock crab within California’s jurisdiction are included in the context of these regulations. California has jurisdiction over crab harvested from waters of California and the Pacific Ocean off this state for commercial purposes. However, other species of crab, and Dungeness or rock crab harvested outside of California’s jurisdictional boundaries, are not included in the context of these regulations.

Adopt the term “crab sample set” to mean all whole crab collected during a sample gathering event from a sample site. The Department proposes a sample set of six crab to be consistent across the states of Washington, Oregon, and California to facilitate uniform regulation and conform to federal standards.

Adopt the term “Department Evisceration Order” to mean an authorization from the California Department of Public Health allowing evisceration of Rock crab or Dungeness crab from specific biotoxin management areas after the Department has determined that the domoic acid in the viscera sample exceeds the action level but the

corresponding meat sample is below action level. The meat can be salvaged and rendered safe for human consumption.

Adopt the term “harvest location” that is consistent with Oregon’s definition in Oregon Administrative Rules section 603-025-0410, requirements for Dungeness Crab. Harvest locations within biotoxin monitoring areas are gridded and numbered into individual blocks to identify the original source of crab. Commercial fishers record the block number from which they harvest crab in order to initiate the documentation required to maintain traceability.

Adopt the term “landing” that is consistent with Oregon’s definition in Oregon Administrative Rules section 603-025-0410, requirements for Dungeness Crab. The landing of crab harvested from a location under Evisceration Order denotes the movement from a commercial fisher’s vessel into the possession of an approved processor. The entire amount of crab in one landing is assigned a unique lot number for traceability purposes.

Adopt the term “lot coding system” to specify that the purpose and technical use of the crab evisceration system is identifying crab source, processing, and distribution information. Lot coding ensures product traceability in case a health issue arises and provides clarity to the regulated community.

Adopt the term “sample site” as the designated sites within each biotoxin management area to facilitate traceback, recall activities, and to maintain consistency with other state agencies and the industry.

Adopt Section 8059 to clarify requirements for crab testing.

Subsection (a) specifies that one sample set must be provided from each of the designated sample sites to make the set valid for regulatory decisions. The Department proposes a sample set of six crab because six is consistent with the requirements for domoic acid crab sampling established in Oregon’s Administrative Rules and the Washington Department of Health’s protocol. This will align sampling operations across the three states, as required to facilitate uniform regulation and promote fair competition.

Subsection (b) clarifies that laboratories may test for domoic acid if they are approved by the Department. Currently, Food and Drug Laboratory Branch is the only certified lab to test for domoic acid in California. This section aims to increase the number of qualified laboratories to ensure reliable testing.

Subsection (c) specifies current action levels for domoic acid, established by the United States Food and Drug Administration, are specified to ensure clarity and public safety. These levels are based on comprehensive data to prevent the consumption of toxic food.

Subsection (c)(1) specifies that United States Food and Drug Administration determined that 30 ppm of domoic acid in Dungeness crab viscera represents a tolerable intake, prompting potential regulatory action. Specifying numeric values ensures clarity and consistency with federal standards.

Subsection (c)(2) specifies that United States Food and Drug Administration determined that less than 20 ppm of domoic acid in Dungeness crab meat is tolerable, setting a threshold for regulatory action. Numeric values promote clarity and align with federal regulations.

Subsection (d) specifies that crab must be tested individually for domoic acid as levels vary, ensuring accurate regulatory decisions. Composite samples could mask high concentrations in individual crabs.

Subsection (e)(1) specifies that all six crab from a sample set representing a sample site must pass viscera action level for the site to pass, a procedure supported by the California Department of Fish and Wildlife and the Office of Environmental Health Hazard Assessment. This procedure has been in use and accepted by the fleet for the past several years.

Subsection (e)(2)(A) is proposed because when domoic acid levels in crab meat reach or exceed 20 ppm, the whole crab is deemed adulterated, leading to area closures to protect consumers. For consistency and to ensure protection of consumers, this is the Department's position in agreement with the California Department of Fish and Wildlife and the Office of Environmental Health Hazard Assessment.

Subsection (e)(2)(B) is proposed because if the viscera fails but meat passes, the meat may be salvaged by means of evisceration. Per statute, the Office of Environmental Health Hazard Assessment, in consultation with the Department, determines if the situation will likely pose a human health risk. The Department may issue an evisceration order.

Subsection (f) specifies restrictions when crab harvested from a biotoxin management area is subject to closure. This section defines the effective time and date for closures.

Subsection (g) specifies when crab harvested from a biotoxin management area subject to evisceration. If a crab sample fails the domoic acid test, all crabs harvested from that area since the collection date must be eviscerated.

Subsection (h) specifies that two consecutive sample sets, taken at least seven days apart, are required to retest from failed sample sites. It takes approximately seven days for domoic acid to dissipate from the viscera and meat. The Evisceration Order may be lifted if both sets are below the action limit, aligning with procedures in Oregon and Washington. The Department, the California Department of Fish and Wildlife and the Office of Environmental Health Hazard Assessment support this procedure.

Adopt Section 8060 to delineate the required actions for approved processors under a Department Evisceration Order. By regulating situations where crab is caught under an evisceration order, and actions an approved processor must take, the Department is preventing public consumption of toxins.

Subsection (a) adopts language that states, per SB 80, all crab caught under a Department Evisceration Order must be sold or transferred to an approved processor.

Subsection (b) to (c) adopts language to specify that processors approved by the Department must receive crab from licensed commercial fishers, ensuring traceability and compliance. Receiving crab from unlicensed sources is prohibited to ensure adherence to safety standards.

Adopt Section 8061 to outline the specific application required to become registered as an approved processor. This amendment is necessary to update the regulations and to provide clarity to the regulated population.

Adoption of subsections (a) to (b) is necessary to create administrative procedures that will regulate the purchases, receipt, evisceration and/or distribution of Dungeness or rock crab. This will subject persons requesting registration to a comprehensive, onsite inspection.

Subsection (a) requires an application for each location, which is consistent with section 110465 of the Health and Safety Code.

Subsection (b) specifies that the applications must include specific business and operational details for recordkeeping and compliance purposes. Contact information for the business operator is essential for regulatory communication.

Subsections (b)(1) to (b)(8) specify that applicants must submit a Hazard Analysis Critical Control Point plan and lot coding system, and have a recall procedure. This ensures safety and compliance with federal and state requirements.

Subsection (c) clarifies that the Department may close or deny an application if a processor failed to fulfill requirements. This allows the Department to focus on reviewing open applications.

Adopt Section 8062

Subsection (a) specified that the evisceration registration is valid for one calendar year. This aligns crab evisceration registration procedures with Processed Food Registration procedures to make them consistent and manageable, as both types of registrations are required for approved eviscerators.

Subsection (b) specifies that a renewal of crab evisceration registration is required. This is consistent with Processed Food Registration procedures.

Subsection (c) clarifies that the Department may suspend or revoke registrations for non-compliance with applicable laws and regulations, which would include the Hazard Analysis Critical Control Point plan, determined during inspections. This is consistent with Processed Food Registration procedures.

For subsection (d) the crab evisceration registration is not transferable to any person. This is consistent with Processed Food Registration procedures.

Adopt Section 8063 to outline the specific requirements for the Hazard Analysis Critical Control Point plan ensuring safety and traceability for products under an Evisceration Order.

Subsections (a) to (f) define the minimum controls that must be addressed in the Hazard Analysis Critical Control Point plan. The plan must address controls for source, storage, evisceration, allergens, lot coding, and other food safety hazards. These measures ensure product safety and effective traceability.

Adopt Section 8064 to outline the specific requirements for the Written Recall Procedures. This section mandates written recall procedures. Evisceration of crab is a high-risk activity, so approved processors must have procedures in place to quickly and effectively trace and recall products if necessary.

Subsection (a) requires recall procedures that address tracing product back to the supplier and forward through distribution. Recall procedures allow for the identification and control of crab source to control further harvest of unsafe crab and allow for the recall of unsafe products to protect public health.

Subsection (b) requires accurate and legible records. Recalls cannot be effective without these.

Subsection (c) requires firms to follow certain specific activities when a recall is necessary to adequately protect the public.

Adopt Section 8065 to outline the specific requirements for the lot coding system and product labeling.

Subsections (a)(1) to (a)(7) set the minimum requirements for a lot coding system. Lot coding systems must address product identity, supplier information, harvest location, receiving date, production date, crab species and quantity, and distribution details. These elements ensure effective product tracing.

Subsection (b)(1) to (b)(4) sets the requirement for labels. Labels for eviscerated crabs must include the lot code, product name, approved processor, and weight. Proper labels help to ensure a safe product and effective product tracing.

Subsection (c)(1) to (c)(2) sets the requirement for labels for retail packaging must also comply with food labeling requirements, ensuring consumer safety.

Adopt Section 8066 to outline the specific requirements for the Recordkeeping.

Subsections (a) to (g) specify the records an approved processor must maintain and provide during an inspection. A review of the records is used to determine if a processor is in compliance with sections 8062-8064.

Subsection (a) documents the source of crab. This includes an approved source or licensed vessel.

Subsection (b) shows the location of harvest. This information can be cross-checked with Evisceration Orders to confirm that the crab came from proper locations.

Subsection (c) allows confirmation of crab source during an Evisceration Order.

Subsection (d) is part of product traceability and record accuracy check in case a problem arises.

Subsection (e) keeps a paper trail of products from receiving to final distribution. These can be used for reconciliation purposes.

Subsection (f) allows the inspector to determine if the approved processor complied with their food safety plans.

Subsection (g) allows the inspector to determine if the approved processor can account for all products produced and distributed.

Adopt Section 8067 to outline unlawful actions regarding eviscerated and uneviscerated crab. These amendments are necessary to update the regulations and to provide clarity to the regulated population. Crab from areas under an Evisceration Order must be sold or transferred to approved processors to ensure safety.

Subsection (a) specifies that it would be unlawful to give away, donate, sell, or offer for sale uneviscerated crab harvested from an area under an Evisceration Order except to approved processors. If a vessel harvests crab from a biotoxin management area under an Evisceration Order, they must sell or transfer all their catch to approved processors. The crab may contain harmful levels of domoic acid if consumed without removing the viscera. Selling or transferring to approved processors would ensure that the crab is properly rendered safe for human consumption. When the viscera are found violative of action level, but the meat is not, then evisceration would remove the harmful viscera and meat can be salvaged for human consumption. These approved processors also have product coding and traceability procedures in place in case a recall is needed. Unpermitted facilities may not adequately comply to ensure public health. The language also means that it is unlawful to give away, donate, sell, or offer for sale uneviscerated

crab directly to retailers or the public. The retailers or public may not be aware of the unsafe levels of domoic acid and its health hazards or may not properly process the crab to prevent health hazards.

Subsection (b) prohibits an approved processor from receiving, holding or eviscerating crab from an area under an Evisceration Order when the Department determined that domoic acid in meat was at or above action level. When meat has unsafe levels of domoic acid, no part of the crab can be salvaged. This subsection prohibits receiving or holding of adulterated crab to prevent unlawful evisceration or comingling.

Subsection (c) clarifies that the Department may take actions against any person falsifying records or failing to comply with requirements, ensuring regulatory adherence.

Subsection (d) prohibits any applicant from making a false and misleading statement or representation, or failing to disclose a fact required to be disclosed on their application. This language describes false and misleading statements as untruthful. Part of the annual Crab Evisceration registration renewal process includes the review of the approved processor's Crab Evisceration Hazard Analysis Critical Control Point plan. If the Hazard Analysis Critical Control Point plan changes in any way since its last Department review, the firm must submit another fee for Hazard Analysis Critical Control Point plan review. There is a possibility that a firm could fail to disclose a change in Hazard Analysis Critical Control Point plan to avoid the additional fee. A change in the Hazard Analysis Critical Control Point plan would not become evident until a facility inspection is conducted. Integrity of all information provided to the Department is critical to protect public health.

Subsection (e) clarifies that altering registration certificates or related documents is prohibited to prevent counterfeit certificates and falsified information.

Subsection (f) prohibits any person from falsifying any document described under this part, so that the Department may have accurate information in implementing the crab evisceration program.